K000122

SEP 2 0 2001

Attachment 16
510(k) Summary Statement for
Collagraft Strip Bone Graft Matrix

I. General Information

Submitter:	NeuColl, Inc. 2500 Faber Place Palo Alto, CA 94303
Contact Person:	Anne Worden
Summary Preparation Date:	January 12, 2000

II. Names

Device Names:	Collagraft Strip Bone Graft Matrix
Primary Classification Name:	Bone Void Filler

III. Predicate Devices

- Osteoset (Plaster of Paris Pellets) marketed by Wright Medical (K963562);
- ProOsteon Resorbable Bone Void Filler manufactured by Interpore International (K980817);
- BoneSource Hydroxyapatite Cement (HAC) manufactured by Osteogenics, Inc. (K964537 and K953339); and
- Colla-Tec Absorbable Collagen Membrane manufactured by CollaTec, Inc. (K924408).

IV. Product Description

Collagraft Strip Bone Graft Matrix is a mixture of purified fibrillar collagen (PFC) and hydroxyapatite/tricalcium phosphate ceramic (HA/TCP). Collagraft Strip Bone Graft Matrix is provided as a sterile, single use, ready to use implantable device that is intended for use as a bone void filler for bony voids or gaps of the skeletal system (i.e., the extremities, spine and pelvis) that are not intrinsic to the stability of the bony structure.

V. Indications for Use

Collagraft Strip Bone Graft Matrix (Collagraft Strip), when coated with autogenous bone marrow, is indicated for use in bony voids or gaps that are not intrinsic to the stability of the bony structure. Collagraft Strip should be gently packed into bony voids or gaps of the skeletal system (i.e., the extremities, spine and pelvis). These defects may be surgically created osseous defects or defects created from traumatic injury to bone. No defect should be greater than 30mL. Collagraft Strip provides a bone void filler that resorbs and is replaced with bone during the healing process.

VI. Rationale for Substantial Equivalence

Collagraft Strip Bone Graft Matrix shares the same indications for use, and therefore is substantially equivalent to both Osteoset (K963562), and ProOsteon Resorbable Bone Void Filler (K980817) as a bone void filler for use in bony voids or gaps of the skeletal system (i.e., the extremities, spine and pelvis) that are not intrinsic to the stability of the bony structure. Collagraft Strip also shares similar indications for use as both BoneSource (for use in the repair of neurosurgical/crainial burr holes - in bone) and Colla-Tec Collagen Membrane (to aid in the healing of peridontal (bone) defects) as bone void fillers. In addition, Collagraft Strip shares similar basic design features and materials as the predicate Osteoset, ProOsteon Resorbable Bone Void Filler, BoneSource HAC (K964537 and K953339), and Colla-Tec Absorbable Collagen Membrane (K924408).

VII. Safety and Effectiveness Information

Scientific literature and previously conducted preclinical and clinical studies demonstrated that Collagraft Strip Bone Graft Matrix is biocompatible and safe and effective for the repair of bone defects and thus is suitable as a bone void filler for voids or gaps of the skeletal system (i.e., the extremities, spine and pelvis).

VIII. Conclusion

Collagraft Strip Bone Graft Matrix was found to be substantially equivalent to the predicate Osteoset bone void filler (K963562) manufactured by Wright Medical, ProOsteon Resorbable Bone Void Filler (K980817) manufactured by Interpore International, the predicate BoneSource Hydroxyapatite Cement (K964537 and K953339) manufactured by Osteogenics, Inc., and the predicate Colla-Tec Absorbable Collagen Membrane (K924408) manufactured by Colla-Tec, Inc.

Collagraft Strip Bone Graft Matrix shares the same indications for use as the predicate Osteoset bone void filler (K963562) manufactured by Wright Medical and by ProOsteon Resorbable Bone Void Filler (K980817) manufactured by Interpore International. In addition, Collagraft Strip Bone Graft Matrix shares similar design and functional features as the currently marketed BoneSource Hydroxyapatite Cement (K964537 and K953339) manufactured by Osteogenics, Inc., and the predicate Colla-Tec Absorbable Collagen Membrane (K924408) manufactured by Colla-Tec, Inc.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 0 2001

Mark R. Alvis, DVM
Director, Research & Development
NeuColl, Inc.
1475 South Bascom Avenue
Suite 100
Campbell, California 95008

Re: K000122
Trade/Device Name: Collagraft® Strip Bone Graft Matrix
Regulatory Class: Unclassified
Product Code: MQV and LYC
Dated: June 21, 2001
Received: June 22, 2001

Dear Dr. Alvis:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Devices Evaluation
Center for Devices and
Radiological Devices

Enclosure

Attachment 2
Indications For Use Statement as Requested by FDA

510(k) Number (if Known): K000122

Device Name : **Collagraft Strip Bone Graft Matrix**

Indications For Use:

Collagraft Strip Bone Graft Matrix (Collagraft Strip), when coated with autogenous bone marrow, is indicated for use in bony voids or gaps that are not intrinsic to the stability of the bony structure. Collagraft Strip should be gently packed into bony voids or gaps of the skeletal system (i.e., the extremities, spine and pelvis). These defects may be surgically created osseous defects or defects created from traumatic injury to bone. No defect should be greater than 30mL. Collagraft Strip provides a bone void filler that resorbs and is replaced with bone during the healing process.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K000122

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)